

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

### Interventional procedure overview of implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery

A cataract is an eye condition in which the lens becomes cloudy over time. If untreated, cataracts can lead to blindness. During cataract surgery, the clouded lens is removed and replaced with an artificial lens, which provides clearer vision. Unlike standard intraocular lenses, a multifocal intraocular lens has areas with different focusing power with the aim of allowing near and distant objects to be seen without the need for spectacles.

#### Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

#### Date prepared

This overview was prepared in November 2007.

#### Procedure name

- Implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery

#### Specialty societies

The following societies were approached to nominate Specialist Advisers

- United Kingdom & Ireland Society for Cataract and Refractive Surgeons
- Royal College of Ophthalmologists
- British Society for Refractive Surgery

## Description

### *Indications*

A cataract is an opacification of the eye's natural lens. It usually develops over a period of time and causes a gradual deterioration in eyesight. Cataracts may eventually lead to blindness. Apart from advancing age, other risk factors for the development of cataracts include diabetes mellitus, and steroid treatment. Cataracts can also follow previous ocular injury, and may also uncommonly occur in childhood as a result of congenital or developmental disorders.

A normal eye has the ability to focus both on near and on distant objects. At rest the eye is set to focus on distant objects. Focusing on near objects requires the contraction of the ciliary muscle, which changes the shape of the lens (and so increases its power). As part of normal ageing, the human lens loses its ability to change shape, such that a spectacle lens is often required to visualise near objects more clearly.

In cataract surgery, the human lens is usually replaced with an artificial lens of fixed power, which therefore requires the individual to use reading spectacles for near vision tasks. In an effort to avoid reading glasses, intraocular lenses have been developed which allow the eye to focus for near and distance vision. These lenses may be multifocal or accommodative in type.

### *Current treatment and alternatives*

Cataract surgery is usually performed under a local anaesthetic, and phacoemulsification is the standard technique used.

During phacoemulsification, after the anterior lens capsule is removed, an ultrasound probe is used to break the lens into tiny pieces, which are removed through a small incision in the cornea. The posterior lens capsule is left in place to support the artificial lens. A flexible intraocular lens is then inserted through the incision, which unfolds once in position inside the eye. The small corneal incision does not usually require sutures. Appropriate measurements of the eye are taken before surgery to select the correct lens power to achieve good sight for distance without spectacles. Accommodating intraocular lenses that have the ability to change shape and have similar properties to a healthy crystalline lens may also be an option for implantation.

### *What the procedure involves*

Phacoemulsification is performed in the same way as conventional treatment, but a multifocal intraocular lens (IOL), rather than a standard intraocular lens, is inserted. The aim of the procedure is to allow the eye to focus on near as well as distant objects without regular need to use glasses. These lenses have areas of different refractive powers and allow both near and distant images to be focused on the retina simultaneously. The brain is then able to select the required image for attention.

## **Efficacy**

One systematic review including 10 RCTs reported that there was no significant difference in the proportion of patients achieving uncorrected distance visual acuity of 6/6 between the multifocal and monofocal groups (odds ratio (OR) 1.05)(95% confidence interval (CI) 0.67 to 1.63). However the proportion of patients achieving a best corrected distance visual acuity of 6/6 was significantly higher in the multifocal group than in the monofocal group (OR 1.67)(95% CI 1.06 to 2.63).<sup>1</sup> However, in the absence of any existing ocular pathology there is no theoretical reason why with best correction there should be any difference in acuity between IOL type.

One non-randomised controlled trial reported that mean near visual acuity (uncorrected) was better following the implantation of a multifocal IOL ( $0.02 \pm 0.12$  logMAR) than with a monofocal IOL ( $0.41 \pm 0.18$  logMAR) ( $p < 0.0001$ ).<sup>2</sup>

One non-randomised controlled trial and one case series reported on the outcome of combined near and distance visual acuity. There was a significantly higher proportion of patients with both distance acuity of 20/40 or better and near acuity of J3 or better with multifocal IOLs (77% [78/101]) than with monofocal IOLs (46% [46/101]) ( $p < 0.0001$ ) in the non-randomised controlled trial<sup>3</sup>; in a case series of 671 patients, 50% of 'best-case' multifocal IOL patients met the same acuity criteria.<sup>4</sup>

One non-randomised controlled trial reported that mean uncorrected visual acuity was improved from 20/40 at baseline to 20/32 at 1-year follow-up following implantation of accommodating IOLs; however, acuity remained the same at 20/32 following implantation of multifocal IOLs.<sup>5</sup>

The systematic review was unable to pool data from primary studies relating to contrast sensitivity owing to the different outcome measures employed in the primary studies. However, all reported lower contrast sensitivity following implantation of a multifocal IOL than with monofocal IOL.<sup>1</sup>

Two of the RCTs included in the systematic review reported a statistically significant increase in patient satisfaction in terms of overall vision with the multifocal IOL compared with the monofocal IOL, while two other RCTs found no significant difference between the groups.

The systematic review reported less dependence on glasses in the multifocal IOL group (68% [316/467]) compared with the monofocal IOL group (95% [383/404]) (OR 0.17 95% CI 0.12 to 0.24).<sup>1</sup> One non-randomised controlled trial and one case series also reported on the extent of spectacle dependence. A significantly higher proportion of patients were able to function without glasses in the intermediate range with multifocal IOLs (92%) than with monofocal IOLs (80%) ( $p = 0.004$ ) (absolute figures not provided).<sup>6</sup> In a second non-randomised controlled trial, frequency of spectacle wear was significantly lower following implantation of a multifocal IOL (never 80%, sometimes 17%, always 3%) than with a monofocal IOL (8%, 69% and 23%, respectively)

IP overview: Implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery

( $p < 0.0001$ ).<sup>2</sup> In a case series of 72 patients, 68% of patients who underwent bilateral implantation with multifocal IOLs remained spectacle free at 8-year follow-up.<sup>7</sup>

## **Safety**

Many of the adverse events described in the literature relate to complications of vision that are related to the design of the multifocal IOL rather than the implantation procedure itself.

A non-randomised controlled trial reported the need for laser capsulotomy for posterior capsule opacification in 29% (7/24) of patients with bifocal IOLs implanted, 25% (8/32) with multifocal IOLs and 12% (3/24) with accommodating IOLs at 1-year follow-up (the level of statistical significance was not reported).<sup>5</sup> In the case series of 72 patients (97 eyes) undergoing multifocal IOL implantation, laser capsulotomy for posterior capsule opacification was required in 56% (54/97) of eyes, at 34-month follow-up after IOL implantation. One patient in this case series had retinal detachment following laser treatment.<sup>7</sup>

The systematic review included results from four RCTs on the outcome of subjective assessment of halos and glare. The pooled data from these studies demonstrated that symptoms occurred significantly less frequently in patients with monofocal IOLs than in those with multifocal IOLs (OR 3.55, 95% CI 2.11 to 5.96).<sup>1</sup> A non-randomised controlled trial reported that 11% of multifocal IOL patients and 1% of monofocal IOL patients reported glare as a severe symptom.<sup>3</sup> A second non-randomised controlled trial reported that, at 3 months, photic symptoms occurred in 61% (11/18) of eyes with one type of multifocal lens, and in 39% (7/18) eyes with another type of multifocal lens; however, this difference was not statistically significant ( $p = 0.121$ ).<sup>8</sup> A third non-randomised controlled trial reported that glare scores were not significantly different between patients with a multifocal IOL (0.80 points) and those with a monofocal IOL (0.93 points) ( $p = 0.0824$ ).<sup>2</sup> A case series of 62 patients reported that halos were reported more frequently in the large-pupil group 93% than the small-pupil group 38% ( $p < 0.001$ ).<sup>9</sup> In the systematic review, two RCTs reported decentration of multifocal IOLs in 8% (3/39) and 12% (3/25) of patients respectively.<sup>1</sup> Given that multifocal IOLs are composite in nature, consisting of multiple lenses, any small decentration will undermine how well they function.

In the case series of 72 patients (97 eyes) undergoing multifocal IOL implantation with 8-year follow-up, 1 patient (<1%) required iris fixation at 2-year follow-up.<sup>7</sup>

One report described the outcome of opacification of the multifocal IOL in 2 patients at 6–8 weeks follow-up.<sup>10</sup> A second case report described a patient with left-eye paracentral scotoma with significantly reduced acuity at 2-day follow-up.<sup>11</sup>

## Literature review

### ***Rapid review of literature***

The medical literature was searched to identify studies and reviews relevant to implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery. Searches were conducted of the following databases, covering the period from their commencement to 06/11/2007 and updated to 31/01/2008: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy.)

The following selection criteria were applied to the abstracts identified by the literature search (Table 1). Where selection criteria could not be determined from the abstracts the full paper was retrieved.

**Table 1 Inclusion criteria for identification of relevant studies**

<b>Characteristic</b>	<b>Criteria</b>
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology.
Patient	Patients with cataracts undergoing phacoemulsification or extracapsular surgery.
Intervention/test	Implantation of multifocal (non-accommodative) intraocular lenses.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

### ***List of studies included in the overview***

This overview is based on one systematic review<sup>1</sup>, six non-randomised controlled trials<sup>5,3,6,2,8,12</sup>, three case series<sup>4,7,9</sup>, and two case reports<sup>10,11</sup>.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) are listed in appendix A.

### ***Existing reviews on this procedure***

One published systematic review with meta-analysis was identified at the time of the literature search, which is summarised in table 2.<sup>1</sup>

**Related NICE guidance**

Below is a list of NICE guidance related to this procedure. Appendix B details the recommendations made in each piece of guidance listed below.

**Interventional procedures**

- Implantation of accommodating intraocular lenses during cataract surgery. NICE interventional procedures guidance 209 (2007). Available from [www.nice.org.uk/IPG209](http://www.nice.org.uk/IPG209)

**Technology appraisals**

None

**Clinical guidelines**

None

**Public health**

None

**Table 2 Summary of key efficacy and safety findings on implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery**

Abbreviations used: BSCVA, best spectacle corrected visual acuity; CI, confidence interval; IOL, intraocular lens; IQR, interquartile range; N/R, not reported; OR, odds ratio; RCT, randomised controlled trial; UCVA, uncorrected visual acuity

Study details	Key efficacy findings	Key safety findings	Comments
<p>Leyland M (2006)<sup>1</sup></p> <p><b>Systematic review – meta analysis</b></p> <p>International studies</p> <p>Study period: (studies published 1992–2004)</p> <p><b>n = 10 RCTs (n = 40–245)</b></p> <p>Allen (1996)</p> <p>El-Maghraby (1992)</p> <p>Javitt (2000)</p> <p>Kamlesh (2001)</p> <p>Leyland (2002)</p> <p>Nijkamp (2004)</p> <p>Percival (1993)</p> <p>Rossetti (1994)</p> <p>Sen (2004)</p> <p>Steinert (1992)</p> <p>Population: varied between primary studies.</p> <p>Indications: Senile cataracts</p>	<p><b>Visual acuity – uncorrected</b></p> <p>There was no significant difference in the proportion of patients achieving 6/6 between the multifocal and monofocal groups (OR 1.05; 95% CI 0.67 to 1.63).</p> <p>There was no significant difference in mean visual acuity between the multifocal and monofocal groups (standardised mean difference 0.03; 95 % CI –0.13 to 0.19).</p> <p><b>Visual acuity – best corrected</b></p> <p>The proportion of patients achieving 6/6 was significantly higher in the multifocal group than in the monofocal group (OR 1.67; 95% CI 1.06 to 2.63).</p> <p><b>Near vision</b></p> <p>It was not possible to pool data from the different studies owing to the poor methodological quality of the primary studies and significant heterogeneity between the study results. All studies reported that near vision was improved with multifocal IOLs.</p> <p><b>Depth of field</b></p> <p>The greater the depth of field the greater the ability of the eye of focus on near or distant objects without spectacle assistance. Four of the RCTs reported on this outcome and all demonstrated improved acuity with minus lens defocus from the distance correction with the multifocal IOL.</p>	<p><b>Glare</b></p> <p>It was not possible to pool data owing to the different outcome measures employed in the primary studies. In one study, acuity in the multifocal group fell as glare increased, from 7.67 lines with no glare to 5.67 with maximum glare. In the monofocal group, acuity fell from 8.19 lines to 6.42 lines (difference not significant).</p> <p>A second study found that differences in acuity between the multifocal and monofocal groups was similar across all illumination levels.</p> <p>A third study found no significant drop in acuity with glare for either IOL type.</p> <p>Four studies included a subjective assessment of glare and halos. These symptoms were significantly less frequent in the monofocal group than the multifocal group (OR 3.55; 95% CI 2.11 to 5.96).</p> <p><b>Complications</b></p> <p>Complications of surgery can be expected to be similar for multifocal and monofocal lenses. Two RCTs reported rates of postoperative IOL decentration in the multifocal arm of 8% (3/39) and 12% (3/25), respectively.</p>	<p>The numbers of participants in each of the primary studies was not always extracted. It was not possible to calculate total number of patients included within the review.</p> <p>Sensitivity analysis was undertaken on the basis of study quality assessment.</p> <p>Interstudy heterogeneity was analysed, and for some outcomes data were not pooled. However, the test for heterogeneity has little power with the small number of studies available for most analyses.</p>

Abbreviations used: BSCVA, best spectacle corrected visual acuity; CI, confidence interval; IOL, intraocular lens; IQR, interquartile range; N/R, not reported; OR, odds ratio; RCT, randomised controlled trial; UCVA, uncorrected visual acuity			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Leyland M (2006) cont.</p> <p>Technique: insertion of refractive or diffractive multifocal lenses (unilaterally or bilaterally) following phacoemulsification or extracapsular extraction vs monofocal IOLs</p> <p><b>Follow-up: (range 1 to 14 months)</b></p> <p>Conflict of interest: varied between primary studies.</p>	<p><b>Contrast sensitivity</b></p> <p>It was not possible to pool data owing to the different outcome measures employed in the primary studies. However, all studies reported lower contrast sensitivity with the multifocal IOL.</p> <p><b>Patient satisfaction with vision</b></p> <p>One RCT reported a small but statistically significant increase in overall visual satisfaction with multifocal IOL 8.4/10 than with the monofocal lens 7.9/10 using a validated scoring instrument (TyPE instrument) One RCT found a statistically significant increase in satisfaction with the multifocal IOL assessed using three different instruments. Two RCTs found no significant difference between multifocal and monofocal IOL in terms of overall subjective satisfaction.</p> <p><b>Spectacle dependence</b></p> <p>Total freedom from glasses was achieved more frequently with multifocal (316/467 dependent) rather than monofocal IOLs (383/404 dependent) (OR 0.17; 95% CI 0.12 to 0.24). However, in all the RCTs, the majority of the patients in the multifocal groups still required glasses for some tasks. Independence from spectacles ranged from 26% to 47%.</p>		<p>TyPE instrument is a self administered questionnaire designed specifically to assess visual disability caused by cataract, with particular emphasis on the need for spectacle correction. There are questions relating to global measures of vision, and frequency of spectacle wear. Vision-related functional status is assessed in questions on distance- and near-vision tasks and glare disability.</p>

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<p>Alió J (2004) <sup>5</sup></p> <p><b>Non-randomised controlled trial</b></p> <p>Spain</p> <p>Study period: not stated</p> <p><b>n = 40 (80 eyes, 32 multifocal)</b></p> <p>Population: mean age 68 years</p> <p>Indications: age 30–80 years; bilateral cataract; in-the-bag IOL implantation.</p> <p>Exclusion criteria: astigmatism &gt; 5.0 D; monocular vision; microphthalmos; aniridia; anterior segment congenital anomalies; macular diseases; retinal detachment; proliferative diabetic retinopathy; previous corneal or refractive surgery; other ocular diseases that may affect the visual outcome.</p> <p>Technique: bilateral implantation of Accommodating lens Crystalens model AT-45 = 12; multifocal lens Array = 16 , or Bifocal lens TwinSet = 12.</p> <p><b>Follow-up: 1 year</b></p> <p>Conflict of interest: none of the authors has a financial or proprietary interest in any material or method mentioned.</p>	<p><b>Mean uncorrected near VA</b></p> <table border="1"> <thead> <tr> <th>Type of IOL</th> <th>Preop</th> <th>1-year follow-up</th> </tr> </thead> <tbody> <tr> <td>Accommodating</td> <td>20/40</td> <td>20/32</td> </tr> <tr> <td>Multifocal</td> <td>20/32</td> <td>20/32</td> </tr> <tr> <td>Bifocal</td> <td>20/63</td> <td>20/25</td> </tr> </tbody> </table> <p><b>Mean best corrected near VA</b></p> <table border="1"> <thead> <tr> <th>Type of IOL</th> <th>Preop</th> <th>1-year follow-up</th> </tr> </thead> <tbody> <tr> <td>Accommodating</td> <td>20/25</td> <td>20/20</td> </tr> <tr> <td>Multifocal</td> <td>20/25</td> <td>20/25</td> </tr> <tr> <td>Bifocal</td> <td>20/25</td> <td>20/25</td> </tr> </tbody> </table> <p><b>Mean uncorrected distance VA</b></p> <table border="1"> <thead> <tr> <th>Type of IOL</th> <th>Preop</th> <th>1-year follow-up</th> </tr> </thead> <tbody> <tr> <td>Accommodating</td> <td>20/40</td> <td>20/25</td> </tr> <tr> <td>Multifocal</td> <td>20/63</td> <td>20/32</td> </tr> <tr> <td>Bifocal</td> <td>20/100</td> <td>20/32</td> </tr> </tbody> </table> <p><b>Mean best corrected distance VA</b></p> <table border="1"> <thead> <tr> <th>Type of IOL</th> <th>Preop</th> <th>1-year follow-up</th> </tr> </thead> <tbody> <tr> <td>Accommodating</td> <td>20/32</td> <td>20/25</td> </tr> <tr> <td>Multifocal</td> <td>20/40</td> <td>20/25</td> </tr> <tr> <td>Bifocal</td> <td>20/40</td> <td>20/25</td> </tr> </tbody> </table> <p><b>Mean add-plus for near vision at 1-year</b></p> <table border="1"> <thead> <tr> <th>Type of IOL</th> <th>Preop</th> <th>1-year follow-up</th> </tr> </thead> <tbody> <tr> <td>Accommodating</td> <td>+2.5 ± 0.9</td> <td>+1.1 ± 0.5</td> </tr> <tr> <td>Multifocal</td> <td>+2.6 ± 0.8</td> <td>+1.0 ± 0.8</td> </tr> <tr> <td>Bifocal</td> <td>+2.8 ± 0.4</td> <td>+0.8 ± 0.7</td> </tr> </tbody> </table>	Type of IOL	Preop	1-year follow-up	Accommodating	20/40	20/32	Multifocal	20/32	20/32	Bifocal	20/63	20/25	Type of IOL	Preop	1-year follow-up	Accommodating	20/25	20/20	Multifocal	20/25	20/25	Bifocal	20/25	20/25	Type of IOL	Preop	1-year follow-up	Accommodating	20/40	20/25	Multifocal	20/63	20/32	Bifocal	20/100	20/32	Type of IOL	Preop	1-year follow-up	Accommodating	20/32	20/25	Multifocal	20/40	20/25	Bifocal	20/40	20/25	Type of IOL	Preop	1-year follow-up	Accommodating	+2.5 ± 0.9	+1.1 ± 0.5	Multifocal	+2.6 ± 0.8	+1.0 ± 0.8	Bifocal	+2.8 ± 0.4	+0.8 ± 0.7	<p><b>1 or 2 lines lost of best corrected near acuity</b></p> <ul style="list-style-type: none"> <li>Accommodating IOL = 0% (0/24)</li> <li>Multifocal IOL = 13% (4/32)</li> <li>Bifocal IOL = 4% (1/24)</li> </ul> <p><b>1 or 2 lines lost of best corrected distance acuity</b></p> <ul style="list-style-type: none"> <li>Accommodating IOL = 0% (0/24)</li> <li>Multifocal IOL = 0% (0/42)</li> <li>Bifocal IOL = 4% (1/24)</li> </ul> <p><b>Patient-reported halos at 1-year follow-up</b></p> <ul style="list-style-type: none"> <li>Accommodating IOL = 8% (2/24)</li> <li>Multifocal IOL = 22% (7/32)</li> <li>Bifocal IOL = 21% (5/24)</li> </ul> <p><b>Patient-reported flare (clouding of an optical system causing dazzle) at 1-year follow-up</b></p> <ul style="list-style-type: none"> <li>Accommodating IOL = 4% (1/24)</li> <li>Multifocal IOL = 6% (2/32)</li> <li>Bifocal IOL = 8% (2/24)</li> </ul> <p><b>Patient-reported flashes at 1-year follow-up</b></p> <ul style="list-style-type: none"> <li>Accommodating IOL = 4% (1/24)</li> <li>Multifocal IOL = 3% (1/32)</li> <li>Bifocal IOL = 4% (1/24)</li> </ul> <p><b>Patient-reported glare at 1-year follow-up</b></p> <ul style="list-style-type: none"> <li>Accommodating IOL = 4% (1/24)</li> <li>Multifocal IOL = 6% (2/32)</li> <li>Bifocal IOL = 8% (2/24)</li> </ul>	<p>Patient selection was not described.</p> <p>There are differences in the preoperative mean uncorrected near and distance visual acuity between the three groups of patients. These differences are not discussed in the paper.</p> <p>In the paper, figures in the abstract and the table disagree with regard to the mean uncorrected near visual acuity for patients receiving the accommodating lens and for those receiving the multifocal lens. The figures presented here are the figures in the table and main body text.</p> <p>Figures in the text and table of the paper disagree with regards to the percentage of patients undergoing capsulotomy. The figures described in the text rather than the table have been used for this overview.</p>
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<p>Lehmann R (2006)<sup>2</sup></p> <p><b>Non-randomised controlled trial</b></p> <p>USA</p> <p>Study period: December 2001 – March 2004</p> <p><b>n = 495 (n = 339 multifocal)</b></p> <p>Population: mean age = 70 years; male = 34%</p> <p>Indications: 21+ years; baseline BSCVA of 0.2 logMAR or worse, astigmatism &lt;1.0D</p> <p>Technique: cataract removal by phacoemulsification. Bilateral implantation of multifocal lens = AD IOL AcrySof lens vs CM-IOL monofocal lens.</p> <p>Objective: to evaluate visual acuity, and patient related outcomes with an multifocal and a monofocal IOL.</p> <p><b>Follow-up: 6 months</b></p> <p>Conflict of interest: supported by manufacturer.</p>	<p><b>Spectacle dependence</b></p> <p>Overall frequency of spectacle wear</p> <table border="1"> <thead> <tr> <th>Type of IOL</th> <th>Never</th> <th>Sometimes</th> <th>Always</th> </tr> </thead> <tbody> <tr> <td>Multifocal n=339</td> <td>80%</td> <td>17%</td> <td>3%</td> </tr> <tr> <td>Monofocal n=156</td> <td>8%</td> <td>69%</td> <td>23%</td> </tr> </tbody> </table> <p>p&lt;0.0001</p> <p><b>Mean uncorrected near VA</b></p> <table border="1"> <thead> <tr> <th>Type of IOL</th> <th>6-month follow-up</th> </tr> </thead> <tbody> <tr> <td>Multifocal</td> <td>0.02 (± 0.12) LogMAR</td> </tr> <tr> <td>Monofocal</td> <td>0.41 (± 0.18) LogMAR</td> </tr> </tbody> </table> <p>p&lt;0.0001</p> <p><b>Mean best corrected near VA</b></p> <table border="1"> <thead> <tr> <th>Type of IOL</th> <th>6-month follow-up</th> </tr> </thead> <tbody> <tr> <td>Multifocal</td> <td>-0.03 (± 0.11) LogMAR</td> </tr> <tr> <td>Monofocal</td> <td>-0.03 (± 0.13) LogMAR</td> </tr> </tbody> </table> <p>p=0.4132</p> <p><b>Mean uncorrected distance VA</b></p> <table border="1"> <thead> <tr> <th>Type of IOL</th> <th>6-month follow-up</th> </tr> </thead> <tbody> <tr> <td>Multifocal</td> <td>0.01 (± 0.12) LogMAR</td> </tr> <tr> <td>Monofocal</td> <td>0.00 (± 0.15) LogMAR</td> </tr> </tbody> </table> <p>p=0.3945</p> <p><b>Mean best corrected distance VA</b></p> <table border="1"> <thead> <tr> <th>Type of IOL</th> <th>6-month follow-up</th> </tr> </thead> <tbody> <tr> <td>Multifocal</td> <td>-0.06 (± 0.09) LogMAR</td> </tr> <tr> <td>Monofocal</td> <td>-0.08 (± 0.10) LogMAR</td> </tr> </tbody> </table> <p>p=0.0039</p>			Type of IOL	Never	Sometimes	Always	Multifocal n=339	80%	17%	3%	Monofocal n=156	8%	69%	23%	Type of IOL	6-month follow-up	Multifocal	0.02 (± 0.12) LogMAR	Monofocal	0.41 (± 0.18) LogMAR	Type of IOL	6-month follow-up	Multifocal	-0.03 (± 0.11) LogMAR	Monofocal	-0.03 (± 0.13) LogMAR	Type of IOL	6-month follow-up	Multifocal	0.01 (± 0.12) LogMAR	Monofocal	0.00 (± 0.15) LogMAR	Type of IOL	6-month follow-up	Multifocal	-0.06 (± 0.09) LogMAR	Monofocal	-0.08 (± 0.10) LogMAR	<p><b>Complications</b></p> <p>Glare (overall) 0 to 4 (lower scores better)</p> <table border="1"> <thead> <tr> <th>Type of IOL</th> <th>6-month follow-up</th> </tr> </thead> <tbody> <tr> <td>Multifocal</td> <td>0.80 (± 0.87)</td> </tr> <tr> <td>Monofocal</td> <td>0.93 (± 0.77)</td> </tr> </tbody> </table> <p>p=0.0824</p>	Type of IOL	6-month follow-up	Multifocal	0.80 (± 0.87)	Monofocal	0.93 (± 0.77)	<p>16-site multicentre study.</p> <p>The patients in the monofocal IOL group were significantly older than those in the multifocal group (mean age 71 and 69 years; p=0.0063). There were no statistically significant difference in any other demographic characteristics.</p> <p>Not all patients responded to all questions relating to patient reported outcomes.</p> <p>Open label study.</p>
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Study details	Key efficacy findings	Key safety findings	Comments
Steinert RF (1999) (cont)	<p><b>Eye clarity</b></p> <p>Fundus photographs of a subset of 23 patients at 2–6 months follow-up showed good to excellent clarity of fundus for both multifocal and monofocal IOL-implanted eyes.</p>		

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<p>Gimbel HV (1991) <sup>6</sup></p> <p><b>Non-randomised controlled trial</b></p> <p>USA and Canada</p> <p>Study period: not stated</p> <p><b>n = 280 (149 multifocal)</b></p> <p>Population: no demographic or clinical characteristics reported.</p> <p>Indications: patients selected on motivation to function without glasses; without astigmatism of eye pathology.</p> <p>Technique: no details given of operative procedure. Bilateral implantation of 3M multifocal IOL.</p> <p>Objective: to report the visual, refractive and patient satisfaction results in a selected subset of patients given bilateral IOLs.</p> <p><b>Follow-up: 29 weeks for multifocal and 50 weeks for monofocal IOLs</b></p> <p>Conflict of interest: manufacturer involved in protocol development and assisted with outcome assessment.</p>	<p><b>Visual acuity</b></p> <p>Group mean and standard deviation</p> <table border="1"> <thead> <tr> <th>Outcome</th> <th>Multi</th> <th>Mono</th> <th>p</th> </tr> </thead> <tbody> <tr> <td>Spherical equivalent</td> <td>0.12D (± 0.16)</td> <td>-0.37D (± 0.79)</td> <td>&lt; 0.05</td> </tr> <tr> <td>Refractive cylinder</td> <td>0.78D (± 0.67)</td> <td>0.92 (± 0.09)</td> <td>0.104</td> </tr> </tbody> </table> <p>Multifocal lenses were planned to produce emmetropia, while monofocal lenses were targeted to be slightly myopic (-0.5D).</p> <p>There were no significant differences in uncorrected visual acuity (p = 0.79) or best corrected visual acuity (p = 0.17) between patients with multifocal IOLs and those with monofocal IOLs.</p> <p>Among patients in the multifocal group, uncorrected near vision was J1 to J2 in 45% of patients and J1 to J3 in 54% of patients (absolute numbers not stated). Near vision data was not regularly collected in the monofocal group and therefore no comparison is possible.</p> <p>A higher proportion of patients reported being able to function without glasses in the multifocal group compared with the monofocal group: distance 93% vs 85% (p = 0.03), intermediate range 92% vs 80% (p = 0.004) and near range 86% vs 32% (p &lt; 0.0001).</p> <p>There was no significant difference in subjective overall rating of vision, with 90% of the multifocal group and 86% of the monofocal group reporting good or excellent vision.</p>				Outcome	Multi	Mono	p	Spherical equivalent	0.12D (± 0.16)	-0.37D (± 0.79)	< 0.05	Refractive cylinder	0.78D (± 0.67)	0.92 (± 0.09)	0.104	<p><b>Visual complications</b></p> <table border="1"> <thead> <tr> <th>Outcome</th> <th>Multi-focal</th> <th>Mono-focal</th> <th>p</th> </tr> </thead> <tbody> <tr> <td>Halos</td> <td>62%</td> <td>8%</td> <td>&lt; 0.05</td> </tr> <tr> <td>Rings</td> <td>46%</td> <td>11%</td> <td>&lt; 0.05</td> </tr> <tr> <td>Flare/glare</td> <td>43%</td> <td>20%</td> <td>&lt; 0.05</td> </tr> <tr> <td>Near vision blur</td> <td>17%</td> <td>8%</td> <td>&lt; 0.05</td> </tr> <tr> <td>Distance vision blur</td> <td>18%</td> <td>5%</td> <td>&lt; 0.05</td> </tr> <tr> <td>Night vision problems</td> <td>15%</td> <td>8%</td> <td>0.07</td> </tr> </tbody> </table> <p>Absolute numbers not stated.</p> <p>Significantly more patients with multifocal lenses (65%) than with monofocal lenses (35%) reported that they required extra light while reading (p = 0.008).</p>			Outcome	Multi-focal	Mono-focal	p	Halos	62%	8%	< 0.05	Rings	46%	11%	< 0.05	Flare/glare	43%	20%	< 0.05	Near vision blur	17%	8%	< 0.05	Distance vision blur	18%	5%	< 0.05	Night vision problems	15%	8%	0.07	<p>Patients were counselled about different IOL options and chose either multifocal or monofocal.</p> <p>Authors state that the cohort for multifocal IOL was highly selected and would only encourage their use in people who are highly motivated not to wear reading glasses and willing to sacrifice some loss of vision.</p> <p>Of 165 patients meeting study criteria, outcomes were available for only 149 (90%). The reason for non-response was not stated.</p> <p>An age- and sex-matched cohort of monofocal patients treated over the same period was selected from patient records.</p> <p>Not all patients were evaluated for all outcomes.</p>
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<p>Chaim PJT (2007) <sup>12</sup></p> <p><b>Non-randomised controlled trial</b></p> <p>UK</p> <p>Study period: May 2005 – June 2006</p> <p><b>n = 100 (n=50 multifocal X2 groups)</b></p> <p>Population: mean age = 68 years, male = 39%.</p> <p>Indications: patients undergoing cataract surgery with astigmatism &lt;1.0 D.</p> <p>Technique: Following standard phacoemulsification, bilateral implantation of ReSTOR or ReZoom multifocal IOL.</p> <p>Follow-up: 6 months</p> <p>Conflict of interest: None</p>	<p><b>Mean near VA</b></p> <table border="1"> <tr> <td>Acuity</td> <td>ReSTOR</td> <td>ReZoom</td> <td>p=</td> </tr> <tr> <td>Uncorrected</td> <td>20/26</td> <td>20/34</td> <td>&lt;0.0001</td> </tr> <tr> <td>Distance corrected</td> <td>20/27</td> <td>20/34</td> <td>0.0007</td> </tr> </table> <p><b>Mean intermediate VA</b></p> <table border="1"> <tr> <td>Acuity</td> <td>ReSTOR</td> <td>ReZoom</td> <td>p=</td> </tr> <tr> <td>Uncorrected</td> <td>20/42</td> <td>20/34</td> <td>0.003</td> </tr> <tr> <td>Distance corrected</td> <td>20/43</td> <td>20/31</td> <td>&lt;0.0001</td> </tr> </table> <p><b>Mean distance VA</b></p> <table border="1"> <tr> <td>Acuity</td> <td>ReSTOR</td> <td>ReZoom</td> <td>p=</td> </tr> <tr> <td>Uncorrected</td> <td>20/23</td> <td>20/21</td> <td>0.091</td> </tr> <tr> <td>Best corrected</td> <td>20/21</td> <td>20/18</td> <td>0.14</td> </tr> </table> <p><b>Spectacle dependence</b></p> <p>86% of the patients in the reSTOR group and 70% of the ReZoom patients did not wear spectacles for daily activities at 6-month follow-up. This difference was not statistically significant (p=0.29).</p> <p><b>Quality of life</b> n=50 for each group</p> <table border="1"> <tr> <td>Overall vision</td> <td>ReSTOR</td> <td>ReZoom</td> <td>p=</td> </tr> <tr> <td>Very satisfied</td> <td>36</td> <td>27</td> <td>0.44</td> </tr> <tr> <td>Satisfied</td> <td>13</td> <td>20</td> <td></td> </tr> <tr> <td>Dissatisfied</td> <td>1</td> <td>3</td> <td></td> </tr> </table> <table border="1"> <tr> <td>Intermediate vision</td> <td>ReSTOR</td> <td>ReZoom</td> <td>p=</td> </tr> <tr> <td>Very satisfied</td> <td>10</td> <td>17</td> <td>0.04</td> </tr> <tr> <td>Satisfied</td> <td>29</td> <td>30</td> <td></td> </tr> <tr> <td>Dissatisfied</td> <td>11</td> <td>3</td> <td></td> </tr> </table>	Acuity	ReSTOR	ReZoom	p=	Uncorrected	20/26	20/34	<0.0001	Distance corrected	20/27	20/34	0.0007	Acuity	ReSTOR	ReZoom	p=	Uncorrected	20/42	20/34	0.003	Distance corrected	20/43	20/31	<0.0001	Acuity	ReSTOR	ReZoom	p=	Uncorrected	20/23	20/21	0.091	Best corrected	20/21	20/18	0.14	Overall vision	ReSTOR	ReZoom	p=	Very satisfied	36	27	0.44	Satisfied	13	20		Dissatisfied	1	3		Intermediate vision	ReSTOR	ReZoom	p=	Very satisfied	10	17	0.04	Satisfied	29	30		Dissatisfied	11	3		<p><b>Complications</b></p> <table border="1"> <tr> <td>Glare</td> <td>ReSTOR</td> <td>ReZoom</td> <td>p=</td> </tr> <tr> <td>None</td> <td>21</td> <td>17</td> <td>0.48</td> </tr> <tr> <td>Mild</td> <td>19</td> <td>18</td> <td></td> </tr> <tr> <td>Moderate</td> <td>10</td> <td>15</td> <td></td> </tr> <tr> <td>Severe</td> <td>0</td> <td>0</td> <td></td> </tr> </table> <p>number of patients, n=50 for each group</p> <table border="1"> <tr> <td>Halos</td> <td>ReSTOR</td> <td>ReZoom</td> <td>p=</td> </tr> <tr> <td>None</td> <td>23</td> <td>14</td> <td>0.10</td> </tr> <tr> <td>Mild</td> <td>20</td> <td>22</td> <td></td> </tr> <tr> <td>Moderate</td> <td>7</td> <td>14</td> <td></td> </tr> <tr> <td>Severe</td> <td>0</td> <td>0</td> <td></td> </tr> </table>	Glare	ReSTOR	ReZoom	p=	None	21	17	0.48	Mild	19	18		Moderate	10	15		Severe	0	0		Halos	ReSTOR	ReZoom	p=	None	23	14	0.10	Mild	20	22		Moderate	7	14		Severe	0	0		<p>Consecutive patient cohorts in each arm. No details of randomisation, allocation concealment, or blinding are described.</p> <p>All procedures undertaken by 3 experienced surgeons.</p> <p>Patients who had intraoperative complications were excluded from the study</p> <p>Patients with a postoperative spherical equivalent of &lt;0.75D of target or cylinder refraction of &lt;0.75D were excluded from the study.</p> <p>There were no differences in demographic or clinical characteristics between the groups at baseline.</p>
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<p>Renieri G (2007) <sup>B</sup></p> <p><b>Non-randomised controlled trial</b></p> <p>Germany and Switzerland</p> <p>Study period: not stated</p> <p><b>n = 18 (n=18 multifocal X2 in fellow eye)</b></p> <p>Population: mean age = 66years, Male = 50%, Baseline BCVA (median ) 0.5D.</p> <p>Indications: Bilateral cataracts, with no other ocular pathology, and astigmatism &lt;1.0D.</p> <p>Technique: Bilateral phacoemulsification with local anaesthetic, and implantation of Array multifocal IOL in one eye and ReSTOR multifocal IOL in the fellow eye..</p> <p>Objective: to compare the visual acuity, contrast sensitivity, and subjective assessment of visual outcome using two different multifocal IOLs with the same patient acting as the control.</p> <p><b>Follow-up: 5 months</b></p> <p>Conflict of interest: Not stated.</p>	<p><b>Median (IQR) distance VA at 3 months</b></p> <table border="1"> <tr> <td>Acuity</td> <td>ReSTOR</td> <td>Array</td> <td>p=</td> </tr> <tr> <td>Uncorrected</td> <td>0.8 (1.0 to 0.63)</td> <td>0.8 (0.8 to 0.63)</td> <td>0.059</td> </tr> <tr> <td>Best-corrected</td> <td>1.0 (1.0 to 0.8)</td> <td>1.0 (1.0 to 0.8)</td> <td>0.48</td> </tr> </table> <p><b>Median (IQR) near VA at 3 months</b></p> <table border="1"> <tr> <td>Acuity</td> <td>ReSTOR</td> <td>Array</td> <td>p=</td> </tr> <tr> <td>Uncorrected</td> <td>0.8 (0.8 to 0.63)</td> <td>0.5 (0.63 to 0.4)</td> <td>0.002</td> </tr> <tr> <td>Distance corrected</td> <td>0.8 (1.0 to 0.8)</td> <td>0.63 (0.63 to 0.4)</td> <td>0.0003</td> </tr> </table> <p>For both these outcomes no changes in VA were recorded at 5 months</p> <p><b>Contrast sensitivity at 5 months.</b></p> <p>There was no significant difference between the eyes with Array IOL (median log contrast sensitivity 1.65 IQR 1.65 to 1.8) and the eyes with the ReSTOR IOL (median log contrast sensitivity 1.65 IQR 1.57 to 1.65) (p=0.581).</p>				Acuity	ReSTOR	Array	p=	Uncorrected	0.8 (1.0 to 0.63)	0.8 (0.8 to 0.63)	0.059	Best-corrected	1.0 (1.0 to 0.8)	1.0 (1.0 to 0.8)	0.48	Acuity	ReSTOR	Array	p=	Uncorrected	0.8 (0.8 to 0.63)	0.5 (0.63 to 0.4)	0.002	Distance corrected	0.8 (1.0 to 0.8)	0.63 (0.63 to 0.4)	0.0003	<p><b>Complications</b></p> <p>There were no intraoperative or postoperative complications</p> <p><b>Visual phenomena</b></p> <p>At 3 months, photic symptoms were reported in 61% (11/18) of eyes with the Array lens, and 39% (7/18) eyes with the ReSTOR lens. (p=0.121).</p> <p>One patient reported disturbing photic phenomena in the eye with the Array lens and this was replaced with a ReSTOR lens after the 3-month follow-up.</p>	<p>All procedures undertaken by one surgeon. Acuity outcomes evaluated by a single observer, no details of independence from the study are described.</p> <p>Optic phenomena were investigated by an independent blinded observer using a standardised questionnaire. With each phenomena rated from 0 (none) to 3 (severe)</p> <p>Only patients who were satisfied with the result after the first eye had been treated were included in the study. Order of first lens implantation was reversed to avoid bias.</p> <p>No drop out was observed.</p>
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<p>Lindstrom RL (1993) <sup>4</sup></p> <p><b>Case series</b></p> <p>International</p> <p>Study period: from 1987</p> <p><b>n = 671</b></p> <p>Population: male = 42%; visual acuity 20/40 or better = 15%, 20/41–20/80 = 47%, 20/81 or worse = 39%.</p> <p>Indications: patients undergoing cataract surgery with no other pathology, 60+ years of age.</p> <p>Technique: no details given of operative procedure. Bilateral implantation of 3M multifocal IOL in most patients (see comments).</p> <p><b>Follow-up: 12 months</b></p> <p>Conflict of interest: not stated</p>	<p><b>Uncorrected distance VA</b></p> <p>Percentage of patients achieving 20/40 or better</p> <table border="0"> <tr> <td>Type of IOL</td> <td>1-year follow-up</td> </tr> <tr> <td>Multifocal</td> <td>57%</td> </tr> <tr> <td>Best case</td> <td>63%</td> </tr> <tr> <td>Monofocal best case</td> <td>69%</td> </tr> </table> <p>Comparisons were non-significant.</p> <p>The proportion of patients achieving functional distance vision was similar across all pupil sizes.</p> <p><b>Uncorrected near VA</b></p> <p>Percentage of patients achieving J3 or better</p> <table border="0"> <tr> <td>Type of IOL</td> <td>1-year follow-up</td> </tr> <tr> <td>Multifocal</td> <td>78%</td> </tr> <tr> <td>Best case</td> <td>82%</td> </tr> <tr> <td>Monofocal best case</td> <td>38%</td> </tr> </table> <p>p &lt; 0.01</p> <p><b>Uncorrected combined near and distance VA</b></p> <p>This outcome was evaluated using the proportion of eyes in each arm that achieved distance acuity of 20/40 or better, and near acuity of J3 or better.</p> <table border="0"> <tr> <td>Type of IOL</td> <td>1-year follow-up</td> </tr> <tr> <td>Multifocal</td> <td>47%</td> </tr> <tr> <td>Best case</td> <td>50%</td> </tr> <tr> <td>Monofocal best case</td> <td>26%</td> </tr> </table> <p><b>Best corrected distance VA</b></p> <p>96% of patients with multifocal lenses achieved BCVA of 20/40 or better.</p>	Type of IOL	1-year follow-up	Multifocal	57%	Best case	63%	Monofocal best case	69%	Type of IOL	1-year follow-up	Multifocal	78%	Best case	82%	Monofocal best case	38%	Type of IOL	1-year follow-up	Multifocal	47%	Best case	50%	Monofocal best case	26%	<p>No safety outcomes reported.</p>	<p>44 participating sites in North America and Europe.</p> <p>Method of case selection and accrual not stated.</p> <p>A subgroup of the total study population (n = 226) received a monofocal lens in the contralateral eye. But no patients received bilateral monofocal IOLs to form a direct control group.</p> <p>The groups in which outcomes were analysed were not well defined. It is not clear whether eyes with multifocal IOL in the group with unilateral implantation are combined with those where bilateral implantation was used.</p> <p>'Best case' patients are those with no other preoperative pathology and no postoperative macular degeneration.</p>
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Lindstrom RL (1993) (cont)	<p><b>Distance corrected near VA</b></p> <p>Functional near vision of J3 or better was achieved in 92% of best case multifocal IOL patients and only 37% of best case monofocal IOL patients (p &lt; 0.0001).</p> <p><b>Spectacle use</b></p> <p>59% of all bilaterally implanted multifocal IOL patients were spectacle free after 12–14-month follow-up.</p> <p><b>Contrast sensitivity</b></p> <p>Outcome evaluated in 162 patients with multifocal and monofocal IOL implantation in contralateral eyes</p> <table border="1"> <thead> <tr> <th>Outcome</th> <th>Multi</th> <th>Mono</th> </tr> </thead> <tbody> <tr> <td>Acuity at 96% contrast</td> <td>20/29</td> <td>20/24</td> </tr> <tr> <td>Acuity at 50% contrast</td> <td>20/37</td> <td>20/29</td> </tr> <tr> <td>Acuity at 25% contrast</td> <td>20/46</td> <td>20/35</td> </tr> <tr> <td>Acuity at 11% contrast</td> <td>20/78</td> <td>20/57</td> </tr> </tbody> </table> <p>Measure of significance not reported.</p> <p><b>Patient satisfaction</b></p> <p>73% (415/568) of patients rated their overall vision in the multifocal eye as 'good', 23% (132/568) as 'fair', and 4% (21/568) as 'poor'.</p>	Outcome	Multi	Mono	Acuity at 96% contrast	20/29	20/24	Acuity at 50% contrast	20/37	20/29	Acuity at 25% contrast	20/46	20/35	Acuity at 11% contrast	20/78	20/57		
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<p>Slagsvold JE (2000) <sup>7</sup></p> <p><b>Case series</b></p> <p>Norway</p> <p>Study period: from 1988</p> <p><b>n = 72 (97 eyes)</b></p> <p>Population: mean age = 78 years.</p> <p>Indications: patients undergoing cataract surgery with no other pathology.</p> <p>Technique: most surgery undertaken with local anaesthesia, implantation of 3M multifocal IOL, bilateral implantation in 35% of patients.</p> <p><b>Follow-up: 8 years</b></p> <p>Conflict of interest: none</p>	<p><b>Uncorrected distance VA</b></p> <p>Percentage of patients achieving 0.5 or better</p> <table border="0"> <tr> <td>Type of IOL</td> <td>8-year follow-up</td> </tr> <tr> <td>Multifocal</td> <td>84%</td> </tr> <tr> <td>Best case</td> <td>90%</td> </tr> </table> <p><b>Best corrected distance VA</b></p> <p>Percentage of patients achieving 0.5 or better</p> <table border="0"> <tr> <td>Type of IOL</td> <td>8-year follow-up</td> </tr> <tr> <td>Multifocal</td> <td>97%</td> </tr> <tr> <td>Best case</td> <td>100%</td> </tr> </table> <p><b>Uncorrected near VA</b></p> <p>Percentage of patients achieving J3 or better tested at 25–40 cm</p> <table border="0"> <tr> <td>Type of IOL</td> <td>8-year follow-up</td> </tr> <tr> <td>Multifocal</td> <td>67%</td> </tr> <tr> <td>Best case</td> <td>74%</td> </tr> </table> <p><b>Distance corrected near VA</b></p> <p>Percentage of patients achieving J3 or better tested at 25–40 cm</p> <table border="0"> <tr> <td>Type of IOL</td> <td>8-year follow-up</td> </tr> <tr> <td>Multifocal</td> <td>83%</td> </tr> <tr> <td>Best case</td> <td>92%</td> </tr> </table> <p><b>Spectacle use</b></p> <p>68% of all bilaterally implanted multifocal IOL patients and 54% of unilaterally implanted patients reported that they were spectacle free.</p>	Type of IOL	8-year follow-up	Multifocal	84%	Best case	90%	Type of IOL	8-year follow-up	Multifocal	97%	Best case	100%	Type of IOL	8-year follow-up	Multifocal	67%	Best case	74%	Type of IOL	8-year follow-up	Multifocal	83%	Best case	92%	<p><b>Complications</b></p> <p>Iris fixation at 2-year follow-up was required by one patient.</p> <p>Laser capsulotomy for posterior capsule opacification was required in 56% (54/97) of eyes, at a mean period of 34 months after IOL implantation.</p> <p>One patient suffered retinal detachment following laser treatment.</p> <p>No lenses were explanted with up to 8 years of follow-up.</p>	<p>Retrospective study</p> <p>This report describes the outcomes of 72 patients of 112 treated (64%). 35 patients had died during follow-up, and five patients were unavailable due to senility or inability to travel for outcome assessment.</p> <p>One surgeon undertook all the IOL insertion procedures.</p> <p>‘Best case’ patients are those with no other preoperative pathology and no postoperative macular degeneration.</p> <p>The authors state that case selection is important, and motivated patients and those with a profession or lifestyle suitable for this lens were encouraged.</p>
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Slagsvold JE (2000) (cont)	<p><b>Operative success</b></p> <p>The IOL was found to be centred in 88% (85/97) of eyes, and in 11 eyes there was insignificant decentration.</p>		

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<p>Salati C (2007)<sup>9</sup></p> <p><b>Case series</b></p> <p>Italy</p> <p>Study period: Aug 2001 to Jan 2003</p> <p><b>n = 62</b></p> <p>Population: mean age = 76 years. Patients were divided into two groups: small pupils (2.5 to 2.9 mm) n=45, and large pupils (3.0 to 5.0 mm) n=17.</p> <p>Indications: patients undergoing cataract surgery with no other pathology, and astigmatism &lt;1.5D.</p> <p>Technique: cataract phacoemulsification surgery with local anaesthesia followed by bilateral implantation of Array IOL .</p> <p>Study aim: to compare how small or large pupils affect VA, spectacle dependency, subjective visual satisfaction, and photic phenomena</p> <p><b>Follow-up: Mean 16.6 months.</b></p> <p>Conflict of interest: none</p>	<p><b>Visual acuity</b></p> <table border="1"> <thead> <tr> <th></th> <th>Small pupil</th> <th>Large pupil</th> <th>p=</th> </tr> </thead> <tbody> <tr> <td>Refractive error</td> <td>0.54 (± 0.73) D</td> <td>0.45 (± 0.65) D</td> <td>N/S</td> </tr> <tr> <td>Near</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Uncorrected VA</td> <td>2.4 (± 1.2) D</td> <td>1.8 (± 0.8) D</td> <td>0.01</td> </tr> <tr> <td>Best corrected VA</td> <td>1.6 (± 0.5) D</td> <td>1.3 (± 0.5) D</td> <td>N/S</td> </tr> <tr> <td>Distance</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Uncorrected VA</td> <td>0.89 (± 0.1) D</td> <td>0.81 (± 0.1) D</td> <td>0.01</td> </tr> <tr> <td>Best corrected VA</td> <td>0.93 (± 0.1) D</td> <td>0.88 (± 0.1) D</td> <td>0.02</td> </tr> </tbody> </table> <p><b>Spectacle Dependence</b></p> <table border="1"> <thead> <tr> <th></th> <th>Small</th> <th>Large</th> <th>P=</th> </tr> </thead> <tbody> <tr> <td>Distance vision</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Not dependent</td> <td>73%</td> <td>47%</td> <td>0.1</td> </tr> <tr> <td>Sometimes</td> <td>13%</td> <td>12%</td> <td></td> </tr> <tr> <td>Dependent &lt;50% of the day</td> <td>13%</td> <td>41%</td> <td></td> </tr> <tr> <td>Distance vision</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Not dependent</td> <td>44%</td> <td>71%</td> <td>0.12</td> </tr> <tr> <td>Sometimes</td> <td>33%</td> <td>12%</td> <td></td> </tr> <tr> <td>Dependent &lt;50% of the day</td> <td>22%</td> <td>18%</td> <td></td> </tr> </tbody> </table> <p>Absolute figures not reported</p> <p><b>Quality of life</b></p> <p>Overall 92% (57/62) of patients were satisfied with their overall postoperative outcome. The difference between the groups was not statistically significant.</p>				Small pupil	Large pupil	p=	Refractive error	0.54 (± 0.73) D	0.45 (± 0.65) D	N/S	Near				Uncorrected VA	2.4 (± 1.2) D	1.8 (± 0.8) D	0.01	Best corrected VA	1.6 (± 0.5) D	1.3 (± 0.5) D	N/S	Distance				Uncorrected VA	0.89 (± 0.1) D	0.81 (± 0.1) D	0.01	Best corrected VA	0.93 (± 0.1) D	0.88 (± 0.1) D	0.02		Small	Large	P=	Distance vision				Not dependent	73%	47%	0.1	Sometimes	13%	12%		Dependent <50% of the day	13%	41%		Distance vision				Not dependent	44%	71%	0.12	Sometimes	33%	12%		Dependent <50% of the day	22%	18%		<p><b>Complications</b></p> <p>Halos were reported more frequently in the large pupil group than the small pupil group (93% vs 38%; p&lt;0.001) absolute numbers not reported.</p> <p>There were no instances of iris prolapse, iris atrophy, persistent corneal oedema, papillary block, retinal detachment, endophthalmitis, or reactive fibrosis in any patient.</p>	<p>All procedures were undertaken by the same surgeon.</p> <p>No details provided of case accrual or selection method, although study report stated that the patients were part of a randomised controlled trial.</p> <p>Independent assessment of pupil size using an autorefractor, and the mean of 3 recordings used.</p>
	Small pupil	Large pupil	p=																																																																						
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Study details	Key efficacy findings	Key safety findings	Comments
<p>Elgohary M (2007)<sup>10</sup></p> <p><b>Multiple case report</b></p> <p>International</p> <p>Study period: not stated</p> <p><b>n = 2 (2 eyes)</b></p> <p>Population: see cases</p> <p>Indications: see cases</p> <p>Technique: local anaesthesia. Phacoemulsification and implantation of array silicone multifocal IOL, unilateral implantation.</p> <p><b>Follow-up: to 6 weeks</b></p> <p>Conflict of interest: part supported by research grant from academic institution.</p>	<p><b>Case 1</b></p> <p>59-year-old woman with multifocal IOL implanted into the left eye. Postoperative visual acuity was 6/6 (Snellen) and decolouration of the optic was noted (not described further). Intraocular pressure was 12 mmHg in both eyes. At 6 weeks, acuity remained at 6/6. However, the patient complained of blurring in the left eye. At 3 months, the IOL was implanted and an acrylic IOL implanted. Clarity of vision was improved and acuity improved to 6/5.</p> <p>Laboratory testing found that there were no deposits on the external surfaces or within the IOL.</p> <p><b>Case 2</b></p> <p>79-year-old woman, with multifocal IOL implanted into the right eye. Postoperatively, the patient had striate keratitis which was treated with topical steroids for 4 weeks. At 8 weeks, corneal oedema resolved, but the IOL was discoloured brown, and the patient complained of blurring of vision. Visual acuity was 6/12 (Snellen) and intraocular pressure was 12 mmHg. Previous cataract and IOL implantation in the left eye was uneventful.</p> <p>The patient decided to have the opacified IOL explanted and replaced. No further follow-up details were provided.</p>		<p>No denominator figure for the total number of patients or eyes treated was provided.</p> <p>Experience of operators was not described.</p> <p>The authors considered lens hydration as the most likely mechanism leading to opacification.</p>

Abbreviations used: BSCVA, best spectacle corrected visual acuity; CI, confidence interval; IOL, intraocular lens; IQR, interquartile range; N/R, not reported; OR, odds ratio; RCT, randomised controlled trial; UCVA, uncorrected visual acuity			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Manzo JL (2002) <sup>11</sup></p> <p><b>Case report</b></p> <p>Spain</p> <p>Study period: not stated</p> <p><b>n = 1 (1 eye)</b></p> <p>Population: see case</p> <p>Indications: see case</p> <p>Technique: local anaesthesia. Phacoemulsification and implantation of MF4 acrylic multifocal IOL, unilateral implantation.</p> <p><b>Follow-up: 1 month</b></p> <p>Conflict of interest: not stated</p>	<p><b>Case 1</b></p> <p>41-year-old woman, with multifocal IOL implantation. On the first postoperative day, split-lamp examination demonstrated a clear cornea and deep anterior chamber. Two days after surgery, the patient was admitted with a left eye paracentral scotoma, and visual acuity was only able to detect hand movement. Ophthalmoscopy revealed an oval hyperpigmented macular lesion of approximately one papillary diameter. Fluorescein angiography indicated a hyperfluorescent ring with central hypofluorescence in the macular area. Ultraviolet filtering sunglasses were given, and 1 ml of triamcinolone acetonide was injected. Oral prednisone was given for 7 days. Visual acuity improved at 1 month, with best corrected visual acuity of 5/20. At 1 year, this was 6/20.</p>		<p>No denominator figure for the total number of patients or eyes treated is provided.</p> <p>The authors stated that this case should draw attention to the possibility of the damaging effect of light on the retina.</p>

### ***Validity and generalisability of the studies***

- The cataract removal technique and the type of multifocal IOL implanted varied between studies.
- A large range of outcome measures were reported, particularly for contrast sensitivity parameters, making direct comparisons between the studies problematic.
- A number of studies in the general literature (none included in table 2) compared visual outcomes between different multifocal IOL designs rather than comparing with monofocal IOLs.
- Some patients included in these studies may have other visual pathologies other than cataracts, which may influence visual acuity. Furthermore, some patients may develop macular degeneration during the follow-up period. Some studies excluded such patients from their analyses.

### **Specialist Advisers' opinions**

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice given is their individual opinion and does not represent the view of the society.

Mr S Prasad (UK and Ireland Society for Cataract and Refractive Surgeons), Mr M Pande (UK and Ireland Society for Cataract and Refractive Surgeons & Royal College of Ophthalmologists), Mr Chawla (UK and Ireland Society for Cataract and Refractive Surgeons), Mr E D Allen (Royal College of Ophthalmologists)

- Three of the Specialist Advisers stated that this is an established procedure, while one commented that the implantation procedure was established however the multifocal lenses are novel.
- The aim of the procedure is to improve the quality of patient vision with improved quality of life, and without dependence on spectacles.
- Adverse events known or reported in the literature include problems with intermediate vision, reduced contrast sensitivity, halos, glare, 'Vaseline vision' / waxy vision and reduced tolerance to astigmatism.
- Additional theoretical events may include difficulty in patients to 'filter out' unwanted images, leading to replacement with monofocal IOL.
- The main comparator would be implantation of a monofocal or an accommodating IOL.
- More than one Specialist Adviser commented that patient selection and counselling are very important
- The surgical technique is well established but accurate biometry and astigmatism control is required in order to produce optimum outcomes.
- There is continual evolution in multifocal IOL design.
- There may potentially be additive effects on visual function in cases of macular degeneration following multifocal IOL implant.
- Two Advisers were unable to predict the potential trajectory of this procedure. One thought that it was likely to be offered in a minority of

hospitals, while another thought that most or all district general hospitals would undertake it.

- Specialist Advisers identified the following key efficacy outcomes, spectacle freedom, unaided near and distance vision, postoperative refractive error, contrast sensitivity, and quality of life.
- Specialist Advisers identified the following key safety outcomes, dysphotopsia, and incidence of exchange for monofocal IOL.

## **Issues for consideration by IPAC**

- Studies of patients with juvenile cataracts have been excluded from this overview.
- A number of non-English-language studies were excluded owing to the considerable evidence base that is available in English.
- Many of the studies included in this overview were published before 2000, with some including patients treated in the 1980s.
- A significant number of studies of various designs are tabulated in appendix A.

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12. Chiam PJ, Chan JH, Haider SI et al. (2007) Functional vision with bilateral ReZoom and ReSTOR intraocular lenses 6 months after cataract surgery. *Journal of Cataract & Refractive Surgery* 33:2057-2061.

## **Appendix A: Additional papers on implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery not included in summary table 2**

The following table outlines studies considered potentially relevant to the overview not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Akaishi L, Tzelikis PF. (2007) Primary piggyback implantation using the ReSTOR intraocular lens: case series. <i>Journal of Cataract &amp; Refractive Surgery</i> 33: 791–5.	Case series  n = 7 (13 eyes)  Follow-up: 12 months	No patients lost lines of BSCVA after surgery.	Larger studies included in table 2  Atypical IOL implantation procedure
Akutsu H. (1992) Contrast sensitivity and reading through multifocal intraocular lenses. <i>Archives of Ophthalmology</i> 110: 1076–80.	Non-randomised controlled trial  n = 28 (7 multifocal)  Follow-up: 4 months	Patients with multifocal lenses demonstrated deficits in reading speeds only with low contrast text.	Larger studies included in table 2
Alfonso JF, Fernandez-Vega L, Baamonde MB et al. (2007) Prospective visual evaluation of apodized diffractive intraocular lenses. <i>Journal of Cataract &amp; Refractive Surgery</i> 33: 1235–43.	Non-randomised controlled trial  n = 670  Follow-up: 6 months	The multifocal IOL provided good visual performance at distance and near under photopic and mesopic conditions.	Comparison of two multifocal IOL designs
Auffarth GU. (1994) Long-term results for glare and contrast sensitivity in patients with diffractive, multifocal intraocular lenses. <i>European Journal of Implant and Refractive Surgery</i> 6: 40–6.	Non-randomised controlled trial  n = 80 (40 multifocal)  Follow-up: 2 years	There were no significant differences when testing contrast sensitivity.	Larger studies included in table 2
Avitabile T, Marano F, Canino EG et al. (1999) Long-term visual results of bifocal intraocular lens implantation. <i>Journal of Cataract &amp; Refractive Surgery</i> 25: 1263–9.	Case series  n = 35  FU=20 months	Diffractive bifocal heparin–surface-modified IOLs provided good visual performance both near and distant.	Larger studies included in table 2
Bellucci R, Giardini P. (1993) Pseudoaccommodation with the 3M diffractive multifocal intraocular lens: a refraction study of 52 subjects. <i>Journal of Cataract &amp; Refractive Surgery</i> 19: 32–5.	Non-randomised controlled trial  n = 72 (52 multifocal)  Follow-up: not reported	Almost perfect vision was achieved when distance refraction was near to emmetropia and astigmatism was minimal.	Larger studies included in table 2

Bi, H., Cui, Y., Ma, X., ET AL (2008) Early clinical evaluation of AcrySof ReSTOR multifocal intraocular lens for treatment of cataract. <i>Ophthalmologica</i> 222 (1) 11-16.	NRCT  n=76 eyes (40 multifocal)  FU=N/S	Uncorrected near visual acuity of 0.5D or better achieved in 93% of multifocal patients. No significant difference in corrected near or distance acuity between the groups	Larger studies included in table 2
Blaylock JF, Si Z, Vickers C. (2006) Visual and refractive status at different focal distances after implantation of the ReSTOR multifocal intraocular lens. <i>Journal of Cataract &amp; Refractive Surgery</i> 32: 1464–73.	Case series  n = 14  Follow-up: 2 months	97% of eyes were within 1D of the manifest refraction spherical equivalent cylinder.	Larger studies included in table 2
Bleckmann H, Schmidt O, Sunde T et al. (1996) Visual results of progressive multifocal posterior chamber intraocular lens implantation. <i>Journal of Cataract &amp; Refractive Surgery</i> 22: 1102–7.	Case series  n = 59 (eyes)  Follow-up: 12 months	Distance UCVA improved from 0.13 Snellen lines to 0.77, and BCVA from 0.23 to 0.96.	Larger studies included in table 2
Boesten IE, Beekhuis WH, Hassmann E et al. (1995) Comparison of the Storz bifocal zonal and the 3M diffractive multifocal intraocular lenses. <i>Journal of Cataract &amp; Refractive Surgery</i> 21: 437–41.	Non-randomised controlled trial  n = 65 (48 multifocal)  Follow-up: 12 months	Postoperatively, all eyes had a best corrected visual acuity of 20/40 or better.	Larger studies included in table 2
Brancato R. (1989) First clinical results of a new multifocal IOL with diffractive optics. <i>Italian Journal of Ophthalmology</i> 3: 35–9.	Case series  n = 10  Follow-up: not reported	No abnormal visual phenomena were reported, and patients reported satisfactory vision.	Larger studies included in table 2
Brydon KW, Tokarewicz AC, Nichols BD. (2000) AMO array multifocal lens versus monofocal correction in cataract surgery. <i>Journal of Cataract &amp; Refractive Surgery</i> 26: 96–100.	Non-randomised controlled trial  n = 28 (15 multifocal)  Follow-up: 75 days	Higher patient satisfaction with multifocal IOL and greater functional independence from spectacle wear.	Larger studies included in table 2

Chen, M., Atebara, N. H., and Chen, T. T. (2007) A comparison of a monofocal Acrysoft IOL using the "blended monovision" formula with the multifocal array IOL for glasses independence after cataract surgery. <i>Annals of Ophthalmology</i> 39 (3) 237-240.	NRCT  n=40 (20 multifocal)  FU=N/S	Similar visual outcomes between the groups	Larger studies included in table 2
Chiam PJT. (2006) ReSTOR intraocular lens implantation in cataract surgery: quality of vision. <i>Journal of Cataract &amp; Refractive Surgery</i> 32: 1459–63.	Non-randomised controlled trial  n = 80 (40 multifocal)  Follow-up: not reported	Spectacle independence was significantly higher with multifocal IOL than monofocal IOL.	Larger studies included in table 2
Claoue C. (2004) Functional vision after cataract removal with multifocal and accommodating intraocular lens implantation: Prospective comparative evaluation of Array multifocal and 1CU accommodating lenses. <i>Journal of Cataract &amp; Refractive surgery</i> 30: 2088–91.	Non-randomised controlled trial  n = 22 (17 multifocal)  Follow-up: 6–18 months	A greater proportion of patients achieved functional near visual acuity with the multifocal IOL than with the monofocal IOL.	Larger studies included in table 2
Dada VK. (1993) Bifocal intra-ocular implants – an Indian experience. <i>Afro-Asian Journal of Ophthalmology</i> 12: 292–4.	Case series  n = 14  Follow-up: 2 months	73% of patients had good distance acuity of 6/12 or better, and 67% had good near vision of N8 or better.	Larger studies included in table 2
Daniel Y, Hennekes R. (1992) Are bifocal intraocular posterior chamber lenses superior to monofocals? <i>Bulletin de la Societe Belge d Ophtalmologie</i> 243: 109–13.	Non-randomised controlled trial  n = 42 eyes (28 bifocal)  Follow-up: to 18 months	In patients with bifocal IOL in one eye and monofocal in fellow eye, no patients preferred the bifocal eye.	Larger studies included in table 2
Dick HB, Krummenauer F, Schwenn O, et al. (1999) Objective and subjective evaluation of photic phenomena after monofocal and multifocal intraocular lens implantation. <i>Ophthalmology</i> 106: 1878–86.	Non-randomised controlled trial  n = 56 (28 bifocal)  Follow-up: to 18 months	No significant difference in halo size between multifocal and monofocal groups.	Larger studies included in table 2

el Maghraby A, Marzouky A, Gazayerli E et al. (1992) Multifocal versus monofocal intraocular lenses. Visual and refractive comparisons. <i>Journal of Cataract &amp; Refractive Surgery</i> 18: 147–52.	Randomised controlled trial  n = 77 (39 multifocal)  Follow-up: 2–4 months	87% of multifocal IOL patients and 71% of monofocal IOL patients had near acuity of J1 to J3. There were no serious complications in either group.	Larger studies included in table 2
Featherstone KA, Bloomfield JR, Lang AJ et al. (1999) Driving simulation study: bilateral array multifocal versus bilateral AMO monofocal intraocular lenses. <i>Journal of Cataract &amp; Refractive Surgery</i> 25: 1254–62.	Non-randomised controlled trial  n = 66 (33 bifocal)  Follow-up: not reported	No differences between multifocal and monofocal groups were seen in 26 of 30 comparisons.	Larger studies included in table 2  Atypical outcome assessment
Fu ER, Yong VS. (1990) Multifocal intraocular lens: a new development in aphakic visual rehabilitation. <i>Annals of the Academy of Medicine, Singapore</i> 19: 817–19.	Case series  n = 104 eyes  Follow-up: 2–12 months	93% of eyes achieved BSCVA (distant) of 6/6 to 6/12. 97% achieved near visual acuity of N5 to N6.	Larger studies included in table 2
Gartaganis SP, Mela I, Michalopoulos E et al. (1991) Clinical trial with diffractive multifocal intraocular lens implantation. <i>Annals of Ophthalmology</i> 23: 448–51.	Case series  n = 25 eyes  Follow-up: to 12 months	Distance UCVA was 0.5 or better in 72% of patients.	Larger studies included in table 2
Ge, X.-F. (2007) Clinical analysis of 20 cases of Array multifocal intraocular lens implantation. <i>International Journal of Ophthalmology</i> 7 (5) 1432-1435.	NRCT  n=43 eyes (22 multifocal)  FU=3 months	There were few operative and postoperative complications in either group. Uncorrected near vision was significantly better in the multifocal group.	Larger studies included in table 2
Goes F. (1991) Personal results with the 3M diffractive multifocal intraocular lens. <i>Journal of Cataract &amp; Refractive Surgery</i> 17: 577–82.	Case series  n = 269 eyes  Follow-up: 3–12 months	98% of 'best case' patients achieved distance visual acuity of 20/40 or better.	Larger studies included in table 2
Gray PJ. (1992) Diffractive multifocal intraocular lens implants for unilateral cataracts in prepresbyopic patients. <i>British Journal of Ophthalmology</i> 76: 336-7.	Case report  n = 5  Follow-up: 14 months	Multifocal IOL considerably improved the quality of life of all patients.	Larger studies included in table 2

Haaskjold E, Allen ED, Burton RL et al. (1998) Contrast sensitivity after implantation of diffractive bifocal and monofocal intraocular lenses. <i>Journal of Cataract &amp; Refractive Surgery</i> 24: 653–8.	Randomised controlled trial  n = 221 (115 bifocal)  Follow-up: 5 months	Contrast sensitivity tended to increase over time after implantation.	Longer follow-up in studies included in table 2
Haring G, Gronemeyer A, Hedderich J et al. (1999) Stereoacuity and aniseikonia after unilateral and bilateral implantation of the Array refractive multifocal intraocular lens. <i>Journal of Cataract &amp; Refractive Surgery</i> 25: 1151–6.	Non-randomised controlled trial  n = 60  Follow-up: 43 months	Despite the simultaneous formation of multiple images, multifocal IOLs allowed good binocular vision.	Comparison of unilateral vs bilateral implantation
Haring G, Dick HB, Krummenauer F et al. (2001) Subjective photic phenomena with refractive multifocal and monofocal intraocular lenses. Results of a multicenter questionnaire. [see comment]. <i>Journal of Cataract &amp; Refractive Surgery</i> 27: 245–9.	Randomised controlled trial  n = 231 (138 multifocal)	18% of patients with multifocal IOL and 4% with monofocal IOL were slightly or moderately bothered by photo phenomena.	Longer follow-up in studies included in table 2
Hayashi K, Hayashi H, Nakao F et al. (2000). Influence of astigmatism on multifocal and monofocal intraocular lenses. [see comment]. <i>American Journal of Ophthalmology</i> 130: 477–82.	Non-randomised controlled trial  n = 60 (30 multifocal)  Follow-up: 1 month	Mean visual acuity in both groups decreased in proportion to the degree of astigmatism.	Larger studies included in table 2
Hayashi K, Hayashi H, Nakao F et al. (2001) Correlation between pupillary size and intraocular lens decentration and visual acuity of a zonal-progressive multifocal lens and a monofocal lens. <i>Ophthalmology</i> 108: 2011–17.	Non-randomised controlled trial  n = 110 (55 multifocal)  Follow-up: 1 month	Smaller pupil size correlated significantly with poorer near visual acuity	Longer follow-up in studies included in table 2
Hutz WW, Eckhardt HB, Rohrig B et al. (2006) Reading ability with 3 multifocal intraocular lens models. <i>Journal of Cataract &amp; Refractive Surgery</i> 32: 2015–21.	Randomised controlled trial  n = 60  Follow-up: 6 weeks	Under bright light conditions, second-generation multifocal IOLs provided better reading performance.	Comparison of three multifocal IOL designs

Jacobi FK. (1999) Bilateral implantation of asymmetrical diffractive multifocal intraocular lenses. <i>Archives of Ophthalmology</i> 117: 17–23.	Case series  n = 95  Follow-up: 6+ months	Multifocal IOLs are a viable alternative to monofocal pseudophakia in prepresbyopic patients with unilateral cataract.	Larger studies included in table 2
Jacobi PC. (2002) Multifocal intraocular lens implantation in prepresbyopic patients with unilateral cataract. <i>Ophthalmology</i> 109: 680–6.	Non-randomised controlled trial  n = 51 eyes (29 multifocal)  Follow-up: 12 months	Multifocal IOLs are a viable alternative to monofocal pseudophakia in patients with traumatic cataract.	Larger studies included in table 2
Jacobi PC. (2003) Multifocal intraocular lens implantation in patients with traumatic cataract. <i>Ophthalmology</i> 110: 531–8.	Case series  n = 29  Follow-up: 3–12 months	80% of patients were completely spectacle free at any time postoperatively.	Larger studies included in table 2
Kamath GG, Prasad S, Patwala YJ et al. (2001) Postoperative myopia with subsequent hyperopic shift after phacoemulsification and multifocal IOL implantation. <i>Journal of Cataract &amp; Refractive Surgery</i> 27: 651–2.	Case series  n = 510  Follow-up: 6 weeks	Some evidence of delayed improvement in acuity with multifocal IOL due to hyperopic shift.	Longer follow-up in studies included in table 2  Not a full study report; only a letter to journal
Kaushik S, Kamlesh. (2002) A clinical evaluation of an aspheric multifocal intraocular lens and its implications for the developing world. <i>Ophthalmic Surgery &amp; Lasers</i> 33: 298–303.	Non-randomised controlled trial  n = 40 (20 multifocal)  Follow-up: 6 months	The loss of contrast sensitivity with multifocal IOLs seems to be an acceptable trade off for satisfactory unaided near vision.	Larger studies included in table 2
Knorz MC. (1993) Results of a European multicenter study of the True Vista bifocal intraocular lens. <i>Journal of Cataract &amp; Refractive Surgery</i> 19: 626–34.	Case series  n = 446  Follow-up: to 11 months	BSCVA was 20/40 or greater in 96% of patients at 4–6 months and 98% of patients at 7–11 months.	Longer follow-up in studies included in table 2

Knorz MC, Koch DD, Martinez-Franco C et al. (1994) Effect of pupil size and astigmatism on contrast acuity with monofocal and bifocal intraocular lenses. <i>Journal of Cataract &amp; Refractive Surgery</i> 20: 26–33.	Non-randomised controlled trial  n = 52 (26 bifocal)  Follow-up: 4+ months	Corneal astigmatism of 0.5D reduces the quality of vision in patients with bifocal IOLs.	Larger studies included in table 2
Kohnen T. (2006) European multicenter study of the AcrySof ReSTOR apodized diffractive intraocular lens. <i>Ophthalmology</i> 113: 584.	Case series  n = 127  Follow-up: 6 months	Multifocal IOL demonstrated excellent near visual acuity without compromising distance vision	Larger studies included in table 2
Lee ES, Lee SY, Jeong SY et al. (2005) Effect of postoperative refractive error on visual acuity and patient satisfaction after implantation of the Array multifocal intraocular lens. <i>Journal of Cataract &amp; Refractive Surgery</i> 31: 1960–5.	Non-randomised controlled trial  n = 188  Follow-up: 3 months	Aiming for emmetropia rather than myopia when calculating lens power with multifocal IOL may improve visual acuity.	Larger studies included in table 2  Subgroup comparison of different postoperative refractive status.
Mester U, Hunold W, Wesendahl T et al. (2007) Functional outcomes after implantation of Tecnis ZM900 and Array SA40 multifocal intraocular lenses. <i>Journal of Cataract &amp; Refractive Surgery</i> 33: 1033–40.	Non-randomised controlled trial  n = 50  Follow-up: 180 days	One multifocal IOL gave better outcomes of near UCVA and distance corrected near VA than a second multifocal IOL.	Comparison of two multifocal IOL designs
Negishi K, Nagamoto T, Hara E et al. (1996) Clinical evaluation of a five-zone refractive multifocal intraocular lens. <i>Journal of Cataract &amp; Refractive Surgery</i> 22: 110–15.	Case series  n = 31  Follow-up: to 6 months	Iris damage occurred in 4% of eyes, vitreous loss in 2%, rupture of Zinn's zonule in 2% and opacification in 4%.	Larger studies included in table 2
Negishi K. (1997) Evaluation of a zonal-progressive multifocal intraocular lens. <i>American Journal of Ophthalmology</i> 124: 321–30.	Case series  n = 22 (36 eyes)  Follow-up: 12 months	Near visual acuity with distance correction was 20/40 in 61% of eyes.	Larger studies included in table 2

Pepose JS. (2007) Visual performance of patients with bilateral vs combination Crystalens, ReZoom, and ReSTOR intraocular lens implants. <i>American Journal of Ophthalmology</i> 144: 347–57.	Non-randomised controlled trial  n = 49  Follow-up: 6 months	A multifocal IOL in one or both eyes was associated with a lower contrast sensitivity and more photic phenomena.	Larger studies included in table 2
Percival SPB. (1989) Prospective study of the new diffractive bifocal intraocular lens. <i>Eye</i> 3: 571–5.	Non-randomised controlled trial  n = 110 (55 bifocal)  Follow-up: not reported	84% of bifocal eyes and 20% of monofocal eyes could read N8 or better with distance correction.	Longer follow-up in studies included in table 2
Post J, Koch DD. (1992) Comparison of depth of focus and low-contrast acuities for monofocal versus multifocal intraocular lens patients at 1 year. <i>Ophthalmology</i> 99: 1658–64.	Non-randomised controlled trial  n = 38 (16 multifocal)  Follow-up: 12 months	Near visual acuity was significantly improved following implantation of multifocal IOLs	Larger studies included in table 2
Richter-Mueksch SW. (2002) Reading performance with a refractive multifocal and a diffractive bifocal intraocular lens. <i>Journal of Cataract &amp; Refractive Surgery</i> 28: 1957–63.	Non-randomised controlled trial  n = 120 (40 multifocal)  Follow-up: not reported	The reading acuity of the multifocal group was significantly lower than in the bifocal or monofocal groups	Larger studies included in table 2
Salati C. (2007) Pupil size influence on the intraocular performance of the multifocal AMO-Array intraocular lens in elderly patients. <i>European Journal of Ophthalmology</i> 17: 571–8.	Case series  n = 62  Follow-up: 16 months	Patients with small pupils at baseline had fewer photic phenomena, and had better visual satisfaction.	Larger studies included in table 2
Sasaki A. (2000) Initial experience with a refractive multifocal intraocular lens in a Japanese population. <i>Journal of Cataract &amp; Refractive Surgery</i> 26: 1001–7.	Case series  n = 31  Follow-up: 6 months	Uncorrected distance acuity was 20/30 or better in 97% of eyes.	Larger studies included in table 2

Schmidinger G, Geitzenauer W, Hahsle B et al. (2006) Depth of focus in eyes with diffractive bifocal and refractive multifocal intraocular lenses. <i>Journal of Cataract &amp; Refractive Surgery</i> 32: 1650–6.	Non-randomised controlled trial  n = 39 (13 multifocal)  Follow-up: 12 weeks	Diffractive IOLs performed better than refractive IOLs	Comparison of three multifocal IOL designs
Sedgewick JH, Orillac R, Link C. (2002) Array multifocal intraocular lens in a charity hospital training program: a resident's experience. [see comment]. <i>Journal of Cataract &amp; Refractive Surgery</i> 28: 1205–10.	Non-randomised controlled trial  n = 31 (17 multifocal)  Follow-up: 10 weeks	Non-significantly greater numbers of patients in the monofocal group used glasses than in the multifocal group ( $p = 0.68$ ), but significantly more used them for near vision ( $p = 0.18$ ).	Larger studies included in table 2
Shoji N, Shimizu K. (1996) Clinical evaluation of a 5.5 mm three-zone refractive multifocal intraocular lens. <i>Journal of Cataract &amp; Refractive Surgery</i> 22: 1097–1101.	Non-randomised controlled trials  n = 40  Follow-up: not reported	There were no significant differences in monocular or binocular visual acuity between the groups.	Comparison of unilateral vs bilateral implantation
Shoji N, Shimizu K. (2002) Binocular function of the patient with the refractive multifocal intraocular lens. <i>Journal of Cataract &amp; Refractive Surgery</i> 28: 1012–17.	Case series  n = 19 (29 eyes)  Follow-up: 13.5 months	93% of patients achieve distance BSCVA of 20/20 or better.	Larger studies included in table 2
Souza CE. (2006) Visual performance of AcrySof ReSTOR apodized diffractive IOL: a prospective comparative trial. <i>American journal of Ophthalmology</i> 141: 827–32.	Non-randomised controlled trial  n = 40 (15 multifocal)  Follow-up: to 180 days	Distance uncorrected and best corrected visual acuity were not significantly different between multifocal and monofocal IOLs.	Larger studies included in table 2

Toto L, Falconio G, Vecchiarino L et al. (2007) Visual performance and biocompatibility of 2 multifocal diffractive IOLs: six-month comparative study. <i>Journal of Cataract &amp; Refractive Surgery</i> 33: 1419–25.	Non-randomised controlled trial  n = 28  Follow-up: 6 months	Diffractive multifocal IOLs were effective in improving functional capacity for distance and near.	Comparison of two multifocal IOL designs
Vanderschueren I. (1991) Multifocal IOL implantation: 16 cases. <i>British Journal of Ophthalmology</i> 75: 88–91.	Non-randomised controlled trial  n = 32 (16 multifocal)  Follow-up: 7 weeks	The multifocal implant has lower initial visual acuity, higher frequency of posterior synechiae, and more difficult ophthalmoscopy, but good near visual acuity	Larger studies included in table 2
Vaquero-Ruano M, Encinas JL, Millan I et al. (1998) AMO array multifocal versus monofocal intraocular lenses: long-term follow-up. <i>Journal of Cataract &amp; Refractive Surgery</i> 24: 118–123.	Non-randomised controlled trial  n = 100 (50 multifocal)  Follow-up: 21 months	Difference between groups in mean distance acuity was not statistically significant.	Larger studies included in table 2
Vingolo EM, Grenga P, Iacobelli L et al. (2007) Visual acuity and contrast sensitivity: AcrySof ReSTOR apodized diffractive versus AcrySof SA60AT monofocal intraocular lenses. <i>Journal of Cataract &amp; Refractive Surgery</i> 33: 1244–7.	Non-randomised controlled trial  n = 70 (50 multifocal)  Follow-up: 6 months	92% of patients with multifocal IOL achieved total spectacle independence	Larger studies included in table 2
Walkow L, Klemen UM. (2001) Patient satisfaction after implantation of diffractive designed multifocal intraocular lenses in dependence on objective parameters. <i>Graefes Archive for Clinical &amp; Experimental Ophthalmology</i> 239: 683–7.	Case series  n = 50 (69 eyes)  Follow-up: 12 months	Emmetropia and low astigmatism are the most important factors for high patient satisfaction.	Larger studies included in table 2
Wang JC. (2005) Experience with ARRAY multifocal lenses in a Singapore population. <i>Singapore Medical Journal</i> 46: 616–20.	Case series  n=27 (45 eyes)  Follow-up: to 6 months	The multifocal IOL showed good efficacy, predictability, stability and safety.	Larger studies included in table 2

<p>Wille H. (1993) Distance visual acuity with diffractive multifocal and monofocal intraocular lenses. <i>Journal of Cataract &amp; Refractive Surgery</i> 19: 251–3.</p>	<p>Non-randomised controlled trial</p> <p>n = 309</p> <p>Follow-up: 4–20 months</p>	<p>The mean postoperative VA was 0.5 lines higher in the monofocal group than the multifocal group (<math>p &lt; 0.01</math>).</p>	<p>Larger studies included in table 2</p>
<p>Williamson W. (1994) Compared optical performances of multifocal and monofocal intraocular lenses (contrast sensitivity and dynamic visual acuity). <i>British Journal of Ophthalmology</i> 78: 249–51.</p>	<p>Non-randomised controlled trial</p> <p>n = 33 (19 multifocal)</p> <p>Follow-up: 19 months</p>	<p>A significant difference in contrast sensitivity for each spatial frequency was found in favour of the multifocal IOLs</p>	<p>Larger studies included in table 2</p>
<p>Zeng M. (2007) Aberration and contrast sensitivity comparison of aspherical and monofocal and multifocal intraocular lens eyes. <i>Clinical and Experimental Ophthalmology</i> 35: 355–60.</p>	<p>Randomised controlled trial</p> <p>n = 124 (39 multifocal)</p> <p>Follow-up: 3 months</p>	<p>Multifocal IOL can improve near vision although it can increase aberration and negatively influence contrast sensitivity</p>	<p>Longer follow-up in studies included in table 2</p>

## Appendix B: Related published NICE guidance for implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery

Guidance programme	Recommendations
Interventional procedures	<ul style="list-style-type: none"> <li>• Implantation of accommodating intraocular lenses during cataract surgery. NICE interventional procedures guidance 209 (2007). Available from <a href="http://www.nice.org.uk/IPG209">www.nice.org.uk/IPG209</a></li> </ul> <p>1.1 Current evidence suggests that there are no major safety concerns associated with the implantation of accommodating lenses for cataract. There is evidence of short-term efficacy in correcting visual acuity but there is inadequate evidence that the procedure achieves accommodation. Therefore, the procedure should not be used without special arrangements for consent and for audit or research.</p> <p>1.2 Clinicians wishing to undertake implantation of accommodating lenses should take the following actions.</p> <ul style="list-style-type: none"> <li>• Ensure that patients understand the uncertainty about the procedure's efficacy, and provide them with clear written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from <a href="http://www.nice.org.uk/IPG209publicinfo">www.nice.org.uk/IPG209publicinfo</a>).</li> <li>• Audit and review clinical outcomes of all patients having implantation of accommodating lenses (see section 3.1).</li> </ul> <p>1.3 Publication of long-term efficacy outcomes of the procedure will be useful, particularly on the effects on accommodation. The Institute will review the procedure in due course.</p>
Technology appraisals	None applicable
Clinical guidelines	None applicable
Public health	None applicable

## Appendix C: Literature search for implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery

IP 682 Implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery		
Database	Date searched	Version searched
Cochrane Library	07/11/2007	Issue 3 2007
CRD databases	07/11/2007	Issue 3 2007
EMBASE	06/11/2007	1980 to 2007 Week 44
MEDLINE	06/11/2007	1950 to October Week 4 2007
PREMEDLINE	06/11/2007	November 05, 2007
CINAHL	06/11/2007	1982 to October Week 4 2007
British Library Inside Conferences	06/01/2007	–
NRR	07/11/2007	2007 Issue 4
Controlled Trials Registry	07/11/2007	–

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in other databases.

1	exp Lens Diseases/
2	Cataract/
3	exp Aphakia/
4	cataract\$.tw.
5	aphakia\$.tw.
6	(Lens adj3 disease\$).tw.
7	or/1-6 (39380)
8	Phacoemulsification/
9	Phacoemulsificat\$.tw.
10	exp Cataract Extraction/
11	Phakoemulsificat\$.tw.
12	(Cataract\$ adj3 extract\$).tw.
13	(Cataract\$ adj3 (extract\$ or remov\$ or

	surg\$)).tw.
14	or/8-13
15	(Multifocal\$ or multi-focal\$ or bifocal\$ or Bi-focal\$ or varifocal\$ or vari-focal\$ or non accommodative\$).tw.
16	Lens Implantation, Intraocular/
17	exp Lenses-Intraocular/
18	(Intraocul\$ adj3 lens\$).tw.
19	IOL.tw.
20	or/16-19
21	7 or 14
22	21 and 15 and 20
23	Restor.tw.
24	rezoom.tw
25	or/23-24
26	22 or 25
27	Animals/
28	Humans/
29	27 not (27 and 28)
30	26 not 29
31	from 30 keep 1-262